Message

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Sent: 2/1/2019 4:25:51 PM
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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

New EPA Science Advisers Include Climate Skeptic, Agency Vets

By Abby Smith

Posted Jan. 31, 2019, 4:29 PM

The EPA's panel of science advisers is getting a slate of new members, including a well-known skeptic of mainstream climate science.

Lead Paint Claim Against N.Y.C. Housing Authority to Proceed

By Peter Hayes

Posted Jan. 31, 2019, 4:23 PM

The New York City Housing Authority faces reinstated lead paint exposure claims based on a report showing a child's blood lead levels increased until the date his mother's apartment was re-painted.

New York to Spend $2.2 Billion to Clean Up Lead Paint in Housing

By John Herzfeld

Posted Jan. 31, 2019, 4:02 PM

New York will spend $2.2 billion to clean up lead paint and other problems in public housing as part of a new, enforceable settlement with federal housing and environmental agencies.

EPA Must Disclose Chemical Safety Studies: House Committee Chair

By Pat Rizzuto

Posted Jan. 31, 2019, 3:36 PM

The Democratic leaders of the House Committee on Energy and Commerce asked the EPA to publicly release all health and safety studies it reviewed on the risks posed by a pigment used in coatings and paints.

Court Must Fast Track Cancer Patient's Asbestos Exposure Suit

By Peter Hayes

Posted Jan. 31, 2019, 2:36 PM

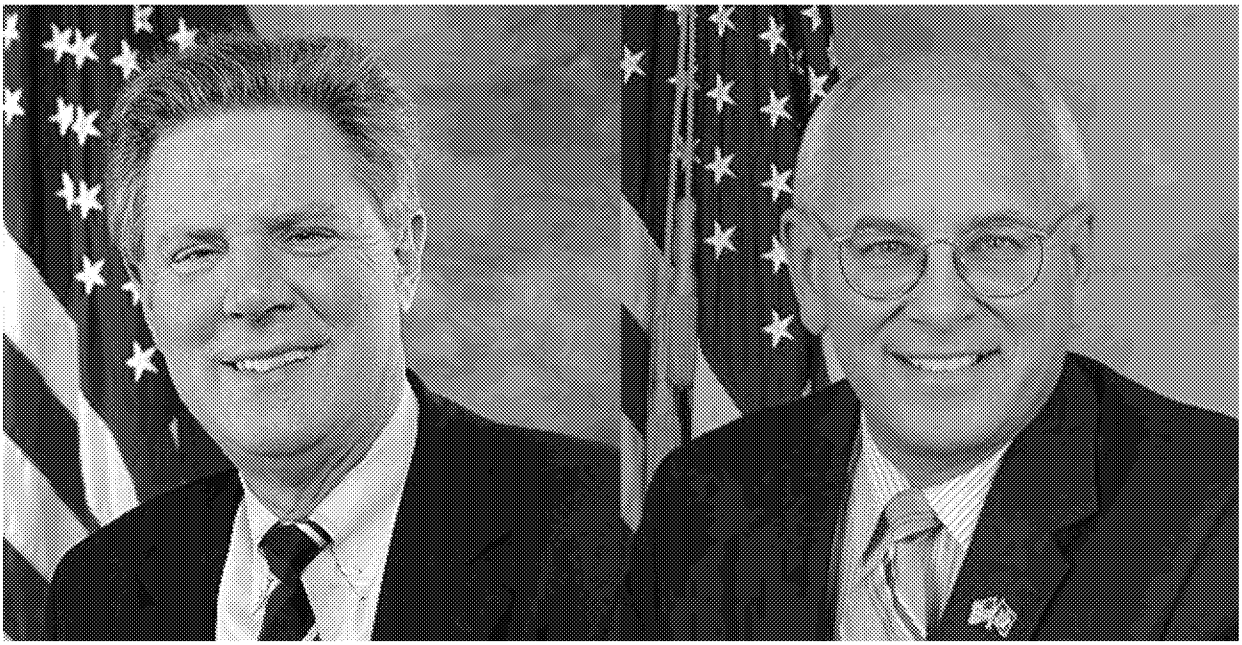
A 75-year old man with advanced and incurable cancer will get an expedited trial in his asbestos exposure lawsuit that's been pending for three years, a California appeals court ruled.

GREENWIRE ARTICLES

Lawmakers press EPA for science behind risk evaluation

Cecelia Smith-Schoenwalder, E&E News reporter

Published: Thursday, January 31, 2019



Democratic Reps. Frank Pallone of New Jersey and Paul Tonko of New York are pressing EPA to release studies on pigment violet 29. US House of Representatives/Wikipedia(Pallone); Paul D. Tonko/Facebook

Democrats on the House Energy and Commerce Committee want to see the science behind EPA's draft risk evaluation for a chemical it determined does not present a human health risk.

Chairman Frank Pallone (D-N.J.) and Environment and Climate Change Subcommittee Chairman Paul Tonko (D-N.Y.) wrote yesterday in a letter to acting EPA Administrator Andrew Wheeler that they were "deeply concerned" at the withholding of certain studies used in the draft risk evaluation for pigment violet 29.

https://www.eenews.net/greenwire/2019/01/31/stories/1060119177

CHEMICAL WATCH ARTICLES

Congressional Democrats turn up the heat on the EPA

31 January 2019 / TSCA, United States

As the EPA reopens after being shuttered for four weeks, Democratic legislators have wasted no time in renewing pressure on the agency.

And the focus of their scrutiny continues to fall on per- and polyfluoroalkyl substances (PFASs), after acting administrator Andrew Wheeler signalled in his recent confirmation hearing that he was unlikely to set an enforceable drinking water standard on the controversial class.

Answers sought on delayed PFAS study

This week, leaders of the House Energy and Commerce Committee reiterated a months-old request for more information on the delayed release of an Agency for Toxic Substances and Disease Registry (ATSDR) study on PFAS.

The study, ultimately released in June 2018, was the subject of significant controversy last year after internal documents surfaced suggesting that the EPA and White House were working to slow its publication.

And House Democrats – including Representatives Frank Pallone (D–New Jersey), Diana DeGette (D–Colorado) and Paul Tonko (D–New York) – said this week they are "deeply concerned that these actions appear to indicate that politics, and potentially industry interests, are being placed before public health, particularly in light of reports that EPA has decided to not set a drinking water limit for several toxic chemicals."

The lawmakers have requested that the EPA respond to its original May 2018 information requests by 12 February.

Wheeler responds to EPW

Meanwhile, the Senate Committee on Environment and Public Works (EPW) top Democrat Tom Carper (D–Delaware) highlighted the lack of action on PFASs as one of several areas of concern amplified by Mr Wheeler's responses to questions raised by the EPW during his nomination hearing.

The written answers were released to the public by Mr Carper's office this week, and address several queries related to the class of substances, including the extent to which the EPA will be evaluating state actions and the ATSDR study in its regulatory process.

Mr Wheeler described the study – which floated minimum risk levels (MRLs) for four PFAS chemicals that are lower than EPA's recommended limits for PFOA and PFOS – as "an important step in the process for establishing a national primary drinking water evaluation".

"As a part of the evaluation, the EPA will continue to carefully review the draft ATSDR toxicological profile and will consider all newly available scientific information, including the science used to develop state standards," he added.

Mr Wheeler's statements also included:

- a commitment to make public the results of a National Academy of Sciences (NAS) review of the agency's methodology for collecting information on general chemical safety, as reflected in a letter he sent to the EPW in January 2019;
- a description of how the partial government shutdown has delayed the agency's continued study of PFASs; and
- and an assurance that a final rule on methylene chloride paint strippers is in interagency review.

Nevertheless, the Democrat's concerns persist.

"I urge my colleagues to join me in urging Mr Wheeler to reverse course on these misguided proposals and restore public confidence in EPA's critical mission," Mr Carper wrote.

Lisa Martine Jenkins

Americas reporter

Related Articles

- Temporary end to US shutdown leaves uncertainty at EPA
- PFAS management plan expected from US EPA in 'very near future'
- House Democrats question ACC role in PFAS controversy
- US ATSDR releases 'suppressed' PFAS tox profile
- White House fears PR 'nightmare' over PFAS risk level
- EPA promises changes to TSCA new chemicals transparency, CBI
- US EPA moves to finalise methylene chloride paint stripper rule

Further Information:

- Letter to Andrew Wheeler from E&C
- Statement by Andrew Wheeler to EPW

Methylene chloride, NMP products remain at major US retailers

Safer Chemicals Healthy Families monitors companies' compliance with 2018 commitments

31 January 2019 / Built environment, Product testing, Retail, United States, Voluntary action

A survey of five major US retailers found that a majority of their stores were still selling methylene chloride or NMP paint strippers, despite the companies' commitments to remove those products from shelves by the end of 2018.

Major home improvement and paint retailers Lowe's, Sherwin-Williams, the Home Depot, Kelly-Moore and Autozone made commitments to phase out the sale of paint strippers containing methylene chloride and N-methylpyrrolidone (NMP) on the back of overwhelming evidence of the substances' health hazards. These were among at least ten retailers that planned to ban the sale of the products.

However, in the first few weeks of 2019, environment and health advocates at Safer Chemicals Healthy Families visited 42 store locations in order to monitor compliance with the agreements. They found that 62% of the stores they visited were still selling either methylene chloride or NMP paint stripper products.

The stores had varying levels of non-compliance with their commitments:

- none of the 12 Lowe's stores surveyed carried products with methylene chloride, but four carried one NMP paint stripper; the company pledged to remove those products when contacted by SCHF;
- none of the seven Sherwin-Williams stores carried NMP-based products, but two stores carried methylene chloride products; a spokesperson for the retailer told SCHF that every store would be re-checked on 18 January, though the company did not respond to a request for confirmation that those checks had been carried out;
- none of the three Kelly-Moore stores visited were still selling paint strippers containing methylene chloride, but one was found to contain NMP; the company's spokesperson told SCHF that they will resend a memo to all Kelly-Moore's stores reminding them of the company's commitment to ban the products;
- all 11 of the Home Depot stores were still selling methylene chloride-based paint strippers and five of 11 also sold NMP-based products; and
- eight of nine AutoZone stores surveyed had methylene chloride products on their shelves, but none had NMP-based paint strippers.

Methylene chloride paint strippers in particular have come under fire from public health advocates because dozens of people have died as a result of using the products. Family members of the victims have joined SCHF and the Vermont Public Interest Research Group to sue the EPA for failure to enact a considered ban on the substance.

The agency issued the original proposal to ban or restrict the two solvents from paint removal applications in early 2017. According to SCHF, at least four people have died from exposure to methylene chloride since then.

Chemical Watch approached all five retailers for comment but had not received a response at the time of publication.

SCHF plans to similarly monitor other retailers that have made the commitment, such as Walmart. And it praises those who have stepped up for taking actions that are "likely saving lives" and put pressure on regulators to make these market interventions unnecessary.

"This new in-store research underscores why we need federal action and enforcement by the EPA, to ensure that no toxic paint strippers remain on store shelves," said SCHF in a statement.

Late last month, the EPA submitted for interagency review a final TSCA section 6 rule to regulate methylene chloride paint strippers. But the rule will not address NMP products, and there are signals it will exclude occupational uses.

Read document in full: SCHF survey results

Lisa Martine Jenkins

Americas reporter

Related Articles

- Lowe's to phase out methylene chloride, NMP paint removers
- Sherwin-Williams to stop selling methylene chloride paint removers
- Campaigners secure third paint stripper victory with Home Depot
- Three more US companies join methylene chloride phase out
- US EPA sued over delay to methylene chloride paint stripper restriction
- US EPA proposes prohibitions on methylene chloride, NMP
- US EPA moves to finalise methylene chloride paint stripper rule
- Walmart to phase out methylene chloride and NMP paint strippers
- US EPA moves to finalise methylene chloride paint stripper rule

OECD says its chemical work saves €300m annually

EHS programme helps member governments 'optimise the use of their resources'

31 January 2019 / Data, Global

The OECD says its environmental, health and safety (EHS) programme saves member countries and industry an estimated €309m per year.

In its report, *Saving costs in chemicals management how the OECD ensures benefits to society*, the organisation says estimated savings have grown by 75% since 2010 and by 240% since 1998.

The savings are spread across industrial chemicals, biocides and pesticides (see table).

Its EHS programme helps member governments "optimise the use of their resources, reduce non-tariff barriers to trade, and save industry time and money by cooperating to test and evaluate the safety of industrial chemicals, pesticides, biocides, nanomaterials and products of modern biotechnology".

OECD countries:

- agree on overall policies;
- develop harmonised instruments for their implementation; and
- set frameworks for, and participate in, work-sharing.

Data acceptance

Much of the savings are accrued through the EHS programme's Mutual Acceptance of Data (MAD) system, which includes the Guidelines for the Testing of Chemicals and the Principles of Good Laboratory Practice (GLP).

The OECD says MAD saves the chemicals industry the expense of duplicate testing for products that are marketed in more than one country. It also provides a "common basis for cooperation among national authorities and avoids creating non-tariff barriers to trade".

In addition, since 2010 there has been an increase in the number of OECD member countries and non-member full adherents to the MAD. "This means that the reduction in duplicative testing is now spread across more countries and hence the savings are greater," it says.

The report adds the OECD's EHS Programme provides a forum for countries to exchange technical and policy information, which creates greater confidence in, and acceptance of, each other's approaches. This "ultimately fosters more efficient, effective and more closely harmonised national chemicals management programmes".

The OECD is trying to get China on the MAD programme.

In addition to financial savings, the OECD says its programme has saved 32,702 animals from being used to test industrial chemicals.

Non-quantifiable benefits

The organisation says the quantifiable savings "only tell part of the story".

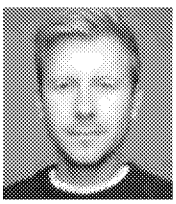
The report also describes the programme's "equally important non-quantifiable benefits", such as:

- harmonised tools for testing and assessing nanomaterials, generating savings to governments and industry;
- harmonised tools to identify the risks of endocrine disruptors;
- harmonised templates for reporting information used for the risk assessment of chemicals; and
- reduced need for national government inspections of chemical test facilities in other countries.

The estimated savings, it says, are just a snapshot of the benefits that have already accrued, and this figure is expected to rise as the results of more EHS projects become available in the coming years.

Annual savings from EHS programme. Source OECD.

Savings	
From no repeat pesticide testing	EUR 206 937 500
From no repeat new industrial chemical testing	EUR 44 728 943
From no repeat biocide testing	EUR 61 250 000
From no repeat existing chemical testing	EUR 780 570
From harmonised pesticide monographs	EUR 2 218 145
From harmonised pesticide dossiers	EUR 1 951 125
Savings subtotal (rounded)	EUR 317 870 000
Costs	
Country participation in the EHS Programme	EUR 4 290 000
OECD Secretariat	EUR 4 545 000
Costs subtotal (rounded)	EUR 8 835 000
Net savings (rounded) EUR 309 035 000	
Reduction in animals needed for testing new industrial chemicals 32 702	



Leigh Stringer

Global Business Editor

Related Articles

- OECD wants closer ties with China on chemical safety

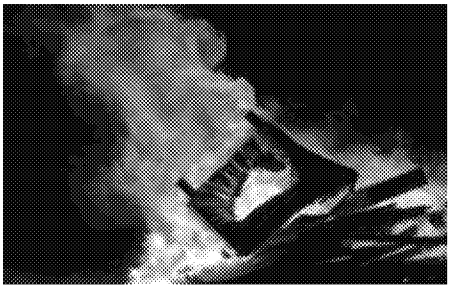
Further Information:

- Report
- Report highlights

California repeals business furniture flammability standard

State also begins allowing flame retardant-free building insulation

31 January 2019 / Built environment, Halocarbons, Standards, United States



California has repealed a flammability standard for upholstered seating used in public spaces. The move will enable the seating to meet state requirements without the use of chemical flame retardants more easily.

On 22 January the state's Bureau of Electronic and Appliance Repair, Home Furnishings and Thermal Insulation (Bearhfti) repealed Technical Bulletin (TB) 133 – The Flammability Test Procedure for Seating Furniture for Use in Public Occupancies. In place since 1991, the standard had been developed to establish fire performance standards for furniture used in public settings, and included an 'open flame' test that was typically met through the use of flame retardants.

But in a statement of reason, Bearhfti said TB 133 has become "obsolete" in most areas, as it overlaps with the recently updated TB 117-2013.

Furthermore, it said, the use of organohalogen flame retardants typically used to meet TB 133 "present significant health risks to consumers, as established by overwhelming scientific research.

"The combination of confusion between the standards and the added health risks to consumers shows a clear need for a change to the regulatory language."

Mixed reactions

California's move has been welcomed by furniture manufacturers and consumer safety advocates alike.

The Business and Institutional Furniture Manufacturers Association said it has urged the repeal of TB 133 for several years and that it worked with a range of groups to advance the change. "Bifma took the lead on the repeal project with presentations, cost studies, surveys, statistical reviews of fire data, and other activities that proved the repeal an appropriate decision for California," it said in a statement.

Arlene Blum, executive director of the Green Science Policy Institute, added that the move was a "win for both healthier furniture and fire safety."

But the North American Flame Retardant Alliance told Chemical Watch that repealing the open flame test would "reduce fire safety by weakening the fire performance requirements".

"Experts have long-considered upholstered furniture one of the consumer products with the greatest fire risk, while decades of experience show fire safety requirements have the greatest impact when applied to public occupancies where loss can be multiplied and more severe," said Nafra.

California allows flame-retardant free building insulation

Meanwhile, the California Building Standards Commission has updated its state building codes to allow for the use of flame retardant-free foam building insulation in below-grade applications.

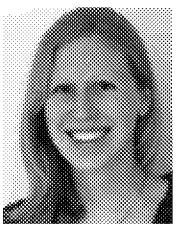
The change will permit the use of foam insulation containing no flame retardants when installed below a minimum 3.5-inch thick concrete slab on grade. Certain labelling requirements apply for such products to prevent their misuse in vertical or above-grade applications, which must continue to meet certain surface burning characteristics.

The proposal had the backing of a wide array of NGOs, architecture firms, corporations, and firefighters. But it was opposed by foam insulation groups and the American Chemistry Council (ACC), who cited concern that the proposal is unjustified and would increase fire danger.

The Office of the State Fire Marshal (OSFM), however, said in its proposal that the scope is limited to an area that "would pose the lowest fire threat", and that testing confirms it will not create a fire hazard.

The GSPI – which has been championing removing flame retardants from building insulation for a decade – said California's move represents "a beginning step towards flame retardant-free building insulation".

A similar code change proposal has been submitted to the International Code Council for consideration later this year, added the NGO.



Kelly Franklin

North America editor

Related Articles

- California proposes change to furniture fire safety regulation
- California approves new upholstered furniture flammability standards

Further Information:

- TB 133 repeal
- Statement of reason
- Bearhfti regulatory changes
- CBSC proposal
- CBSC January 2019 proposals
- CBSC statement of reason
- GSPI blog

Echa round-up

31 January 2019 / CLP Regulation, Europe, REACH

Targeted public consultation

Echa has begun a targeted public consultation on additional information provided for a proposal for harmonised classification and labelling on 1-isopropyl-4-methylbenzene. In this the lead registrant has indicated the availability of an unpublished acute toxicity study in *Daphnia magna* that could change the classification proposal.

A public consultation is open until 11 February 2019.

CLH proposals and intentions

Echa has received proposals to harmonise the classification and labelling for:

- N,N-dimethyl-p-toluidine. Germany is proposing harmonised classifications of acute toxicity 3 and 4, carcinogenicity 2, and Stot RE 2. And specific concentration limits of Oral: ATE = 139 mg/kg bwInhalation: ATE = 1,4 mg/L (mists); and
- 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid. Austria is proposing a harmonised classification of reproductive toxicity 1B, H360FD.

It has also received a new intention for:

- 2-ethyl-2-[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl diacrylate. France is proposing harmonised classifications of carcinogenicity 2, aquatic acute 1, M-factor=1 and aquatic chronic 1, M-factor=1.

Testing proposals

And the agency has invited third parties to submit scientifically valid information and studies on five testing proposals on the following four substances:

- 1,3,2-dioxathiolane 2,2-dioxide
- N-(3-aminopropyl)-N'-C16-18 (evennumbered), C18 unsaturated alkyl -propane-1,3-diamine
- reaction mass of N,N,N',N'-tetrabutylmethylenediamine and dibutylamine
- reaction products of acrylic acid with 2,2'-[oxybis(methylene)]bis[2-ethylpropane-1,3-diol]

The deadline for submitting information is 11 March.

Board of Appeal announcements

The BoA has published announcements of two new appeals related to data-sharing disputes:

- in case A-024-2018, the appellant Symrise AG, Holzminden is the lead registrant of the substance 3-phenylpropan-1-ol; and
- in case A-023-2018, the appellant Oxiteno Europe SPRL is lead registrant of the substance isopenyl acetate.

In both, the appellants are asking for the decision to be annulled in which Echa decided they had failed to make every effort to reach an agreement with the claimant, another registrant of the substance, over data-sharing.

Guidance

Echa has released a guide on how to act during dossier evaluations. The document explains how dossiers are processed and how registrants should act after receiving the draft or adopted decision.

It also highlights changes that have come in since 1 January. These have meant that dossier decisions are sent to all non-compliant registrants of a substance.

The agency has also released a guide on how to report changes in identity under the REACH and CLP Regulations. This latest document replaces 'Practical guide 8: How to report changes in identity of legal entities'.

The latest guide is available in English, with translations are expected at a later date.

EUON

The EU observatory for nanomaterials is seeking topic suggestions for future studies on nanomaterials. EUON conducts at least three studies a year to address knowledge gaps that are of interest to the general public and the research community.

It is looking for studies that address:

- questions relating to the health and safety of nanomaterials, including hazard and risk assessment, exposure or worker safety and protection;
- specific issues surrounding consumer or worker uses.
- markets for nanomaterials, focusing on those in the EU.

The scope can be on nanomaterials in general, a specific nanomaterial, or a defined group and it should be possible to execute within three to nine months.

The studies should be based on desk research and surveys and not require experimental facilities, for example for conducting animal or other laboratory studies, it says.

The outcome and study reports will be made publicly available on the EUON website.

If a topic is selected, the proposer may be contacted for further information. The deadline for proposals is 7 February.

And the agency is also seeking feedback, via a short questionnaire, on how its European Observatory for Nanomaterials (EUON) is performing and could be improved to better meet the needs of users.

The resource provides information on nanomaterials, on a range of subjects from safety to innovation to a wide audience. It covers existing EU legislation and the presence and uses of specific substances on the EU market.

Seac draft opinion reminder

The agency has issued a reminder that it wants comments on the draft opinion released by its Socio-economic Analysis commitee(Seac) on the proposed restriction of hazardous substances in tattoo inks and permanent make-up.

Echa prepared the proposal along with Denmark, Italy and Norway.

The deadline for comments is 11 February 2019.

Related Articles

- Major revamp of REACH dossier compliance processes announced

- Echa's committees unable to conclude on tattoo derogations

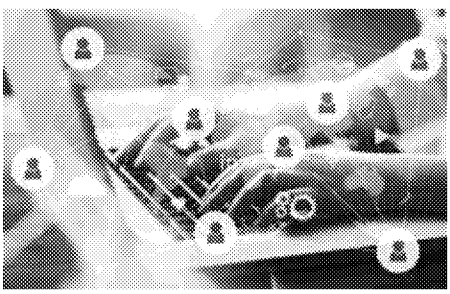
Further Information:

- Targeted public consultation
- Registry of CLH intentions until outcome
- Registry of intentions
- Testing proposals
- Appeal announcements
- Dossier evaluation guidance
- Changes in identity guidance
- EUON
- EUON survey
- Seac reminder

EU drafting Implementing Regulation for new substances registration

Commission considering a second for dossiers

31 January 2019 / Europe, REACH, Substance registration



The European Commission is preparing an Implementing Regulation under REACH to spell out registration procedures for new substances on the market, Commission sources have told Chemical Watch. And another may be on the way to toughen up the requirements for dossier updates.

It is intended that the first Implementing Regulation, still in draft form, will explain how REACH registration provisions will operate following the expiry in June 2018 of the transitional regime that applied to 'phase-in' substances. These are chemicals that were already on the market when REACH was adopted in 2007.

Echa has received dossiers for 21,551 phase-in chemicals and believes the majority of the substances currently used on the market have been registered, even as NGOs say there may be thousands of unregistered chemicals.

The Commission said the new Implementing Regulation would aim to provide clarifications regarding:

- calculation of tonnage in registering substances;

- applicability of reduced REACH registration requirements; and
- continuing obligations of existing registrants of phase-in substances to jointly update their registration dossiers after 1 June 2018.

No further details have yet been revealed, but the draft Regulation is currently going through the Commission's "internal procedures and obligations" and member states will vote on it in the context of the REACH Committee.

"The Commission's intention is that the vote will take place in the first quarter of 2019," a source said.

Article 22

The Commission is also considering drafting another Implementing Regulation to boost the frequency at which registration dossiers are updated, amid concerns over high levels of non-compliance in REACH dossiers.

Some EU member states and Norway have called for an implementing Act to clarify Article 22 of REACH, to ensure companies regularly review and update dossiers. The Commission's second REACH review called for actions to encourage dossier updates and, last September, Echa announced a major revamp of compliance processes.

The EU executive is mulling "what options are available", the Commission said, and they include an implementing act that would provide "further detail regarding the timing and circumstances in which dossiers need to be updated".

It will also propose amending Echa's compliance target, currently set at 5% of dossiers registered under each tonnage band. The new target should be "a further incentive" for companies to comply with registration duties, the Commission said. It did not disclose the new target.

Echa is already using "intelligent strategies" to prioritise compliance checks, it added, but it could also consider "amending or adding new criteria" for prioritisation "to achieve the highest impact with dossier evaluation."

A German study last year found registration dossiers to be non-compliant for some 32% of substances at 1,000 tonnes per year or above. Echa's seventh enforcement project (Ref-7) started in January and will focus on dossier compliance.

Cefic said it would welcome a draft Implementing Regulation on Article 22 as it would provide more clarity "on what needs to be updated in dossiers and when."

The clarification will be helpful for everyone, Cefic said, "for authorities to better assess whether a dossier needs to be updated or not and for registrants to proactively update their entries, if needed."

Clelia Oziel

EMEA correspondent

Related Articles

- More than 21,000 substances registered under REACH

- Echa's 2018 REACH registration numbers get mixed reception
- EU states call for REACH dossier update Regulation
- EU publishes delayed second REACH Review
- Major revamp of REACH dossier compliance processes announced
- REACH registration project finds low compliance rates
- Echa: 'Army' of inspectors to probe REACH registrations

Nestlé releases 'negative list' of plastic packaging materials

31 January 2019 / Food & drink, Switzerland, United States, Voluntary action

Nestlé has identified a number of plastic materials it will not use in its product packaging because it says they are difficult to recycle.

The "Negative List" was announced earlier this month. Nestlé intends to phase out the substances' use in existing packaging, and has also placed a ban on their use in new packaging.

The excluded substances include:

- polyvinyl chloride (PVC);
- polyvinylidene chloride (PVDC);
- polystyrene (PS);
- expanded polystyrene (ePS);
- regenerated cellulose; and
- non-recyclable plastics/paper combinations.

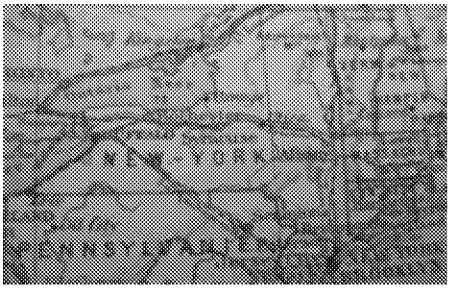
Further Information:

- Nestlé 'negative list

New York governor announces proposal to expand ingredient disclosure

Andrew Cuomo floats 'Consumer Right to Know Act'

31 January 2019 / Confidentiality & right-to-know, United States



New York governor Andrew Cuomo has announced a proposal to require on-package labelling and increased ingredient disclosure for consumer products.

The concept, announced as part of his executive budget proposal, would authorise the state's Department of Environmental Conservation to require labelling for certain consumer products, and expand existing cleaning product ingredient disclosure requirements to personal care products.

"There are 1,000 known carcinogens that are in products that are used every day," the governor said. "We want to pass a Consumer Right to Know Act that labels those products that have those carcinogens".

Consumer product labelling

Details of the draft legislation, outlined in the governor's 2020 executive budget legislation package, call for granting the state's environmental department the authority to establish a consumer product labelling standard to inform consumers of products containing "any carcinogen, mutagen, endocrine disruptor or other chemicals of concerns identified by the department".

This could extend to children's products, cleaners and any other product that could expose a user to a concerning substance through normal use.

The proposal also calls for reporting requirements and the development of a public education programme, which could include a requirement for retailers to post information for consumers' benefit.

Personal care products

A separate article in the draft legislation takes specific aim at personal care products.

Existing federal laws that require ingredient disclosure for these, it says, "fail to adequately educate and protect consumers". The proposal therefore calls for such products to more fully disclose ingredients and to indicate those identified as a chemical of concern on one or more lists.

This, it says, would "benefit consumers, encourage manufacturers to remove potentially harmful chemicals from their products, and encourage development of innovative methods, including green chemistry, to replace these ingredients with more environmentally preferable alternatives".

More specifically, the draft calls for manufacturers to post to their websites and disclose to the state a list of ingredients by weight, as well as relevant health and safety information.

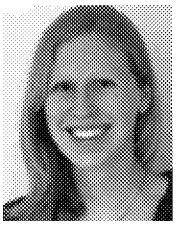
And it stipulates that such information would need to be furnished biennially, as well as:

- prior to the sale of any new personal care product;
- when the formulation of a currently reported product is changed such that the predominance of the ingredients is changed; or

- when any referenced chemical of concern list is updated to include an ingredient present in a product.

"The more we know about our exposure to chemicals, the more frightening the situation is," Governor Cuomo said. "Consumers have the right to know what is in the products they use, and requiring labelling on designated products will provide consumers with the information they deserve."

The governor's office could not be reached by press time for details as to how it plans to advance the legislation.



Kelly Franklin

North America editor

Related Articles

- New York state delays enforcement of cleaning products disclosure

Further Information:

- Cuomo announcement
- NY 2020 executive budget

NGO Platform: The hidden hazards of chemicals in plastics

Global Business Briefing, February 2019 / Global, Phthalates

Dr Anna Watson, CHEM Trust head of advocacy, describes how scientists at the Food Packaging Forum established a comprehensive database of chemicals used in the production of plastic packaging

When I buy fruit and vegetables at my nearest supermarket, I can no longer buy loose mushrooms, onions, apples or potatoes. They all come wrapped in plastic – a close-to-home reminder about how the use of plastic packaging is increasing in our daily lives. Of the 380m tonnes of plastics produced worldwide each year, more than 40% are used in packaging, with the majority of that used in food packaging.

Plastic packaging does not just cause environmental problems with its use of resources, litter and degradation to smaller particles; it is a source of chemical exposure to consumers and workers.

The chemicals used in packaging can migrate into foods and the environment during manufacturing, use, disposal and recycling. It is therefore vital for us to know what chemicals are present in plastic packaging and what the associated risks are, so that we can restrict chemicals that cause harm and replace them with safer alternatives.

Plastic packaging database

Since the summer of 2017, CHEM Trust has been part of a collaboration of NGOs, including the Food Packaging Forum, ChemSec and academic scientists, to:

- identify which hazardous chemicals are used in the manufacturing of plastic packaging and in the end product;
- compile information on their applications and toxicity; and
- identify which substances should be prioritised to be substituted for safer alternatives.

However, it has not been straightforward to determine which chemicals are used in the production of plastic packaging, as there is no single registry for this information. Scientists at the Food Packaging Forum started by trawling through data to establish a comprehensive database.

The scientists faced considerable barriers when building the database due to a lack of information concerning the use of chemicals in plastics manufacturing and the chemicals' function and presence in final products.

This was often caused by information not being publicly accessible through standard search methods or not being accessible at all. In addition, plastic packaging contains impurities, degradation products, and contaminants which cannot be exhaustively compiled because many of these chemicals are not yet identified.

The chemicals associated with plastics packaging database (CPPdb), containing 4,283 substances, was the result of this extensive study. Information on their toxicity and uses in plastic packaging, as well as additional regulatory information such as authorisation for use in food packaging is also included. The 906 substances which are most likely to be associated with plastic packaging have been published on the Data Commons website.

Hazardous chemicals and prioritisation

At least 148 of the 906 chemicals most likely to be associated with plastic packaging were identified as particularly hazardous both to human health and the environment based on several harmonised hazard data sources. Sixty-eight chemicals were identified as particularly hazardous to the environment and 63 chemicals were identified as particularly hazardous for human health.

The next step in the project was to identify which chemicals in plastic packaging should be a priority for the industry to find alternatives.

To achieve this prioritisation, a set of criteria was agreed, combined with the expert judgment of the project partners. It is worth noting that different prioritisation processes will have different outcomes and the result is strongly dependent on the available information.

All the chemicals identified following the prioritisation criteria were ortho-phthalates. Benzyl butyl phthalate (BBP) was selected as the highest-priority substance for environmental hazards in the context of this research project. Five phthalates, including BBP, were selected as the highest priority substances for human health.

The others were: dibutyl phthalate (DBP); diisobutyl phthalate (DiBP); bis(2-ethylhexyl) phthalate (DEHP)and dicyclohexyl phthalate (DCHP).

Ortho-phthalates

All of the prioritised ortho-phthalates in the study are used as plasticisers, adhesives or printing inks in plastic packaging. In Western Europe, we produce about 1m tonnes of phthalates each year, of which approximately 900,000 tonnes are used to plasticise PVC. And, according to the industry, a large proportion of this PVC is used to make rigid and flexible films for packaging.

Phthalates are a well-known problematic group of chemicals for human health, which is why some of the uses of certain phthalates in toys and other children's products are partly restricted in the EU.

The EU has also decided to restrict the use of four of the ortho-phthalates prioritised in our project: DEHP, DBP, BBP and DIBP. Their use in many consumer products will be restricted, due to their toxic effect on reproductive health and the endocrine system. This partial ban takes into account the cumulative effects of combined exposure to the four phthalates. This as a welcome and long overdue measure.

However, the restriction does not prevent these chemicals being used in food contact materials such as conveyor belts and pipes used during food production, plastic gloves worn to handle food, and containers and wrappings used for food packaging. This is a glaring loophole and it must be closed as soon as possible.

Restrictions are also being discussed in the US. Since 2016, the US Food and Drug Administration has been reviewing a petition by public interest organisations to remove approval of 30 phthalates in food contact materials. However, on 14 November 2018 the FDA said it was also considering a petition from an industry group, Flexible Vinyl Alliance, claiming that only four phthalates (DEHP, DCHP, diisononyl phthalate and diisodecyl phthalate) are used in contact with food, including final packaging.

The petition requests that the agency de-authorise the remaining 26 phthalates because their use as food contact substances has been abandoned.

What should the industry do?

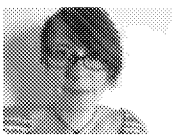
What do the findings of this project mean for industry and regulators? First, the project has exposed how difficult it is to get hold of chemical-use information. We need far more transparency from the industry on the chemicals they are using to produce plastic packaging.

Second, industry must move away from using groups of known hazardous substances such as the phthalates; other research by CHEM Trust has highlighted that bisphenols are a similar problem group. By regulating one chemical at a time the regulators allow the industry to move from one problematic chemical to the next within a group, rather than solving the problem.

We know that the industry can rise to this challenge. In March 2018, food brands in the US, such as Nestlé, and food packaging supply chain companies published the Food Packaging Product Stewardship Considerations. It contains a list of chemicals that these companies do not want to see in their packaging. Ortho-phthalates, including the ones our project has identified, are at the top of the list.

Third, our project identified more than 4,000 chemicals that are likely to be associated with the manufacture of plastic packaging. However, there will be many more chemicals present than we can identify – the so-called non-intentionally added substances (Nias). Not only have most of these chemicals not been identified, they have generally not been risk assessed. We simply cannot say that any plastic packaging is safe without this information.

Ultimately, in order to address the Nias issue, the industry must use fewer chemicals and ensure production processes are controlled in such a way that Nias are identified and appropriately assessed for their health and environmental impacts.



Dr Anna Watson

View transparency statement

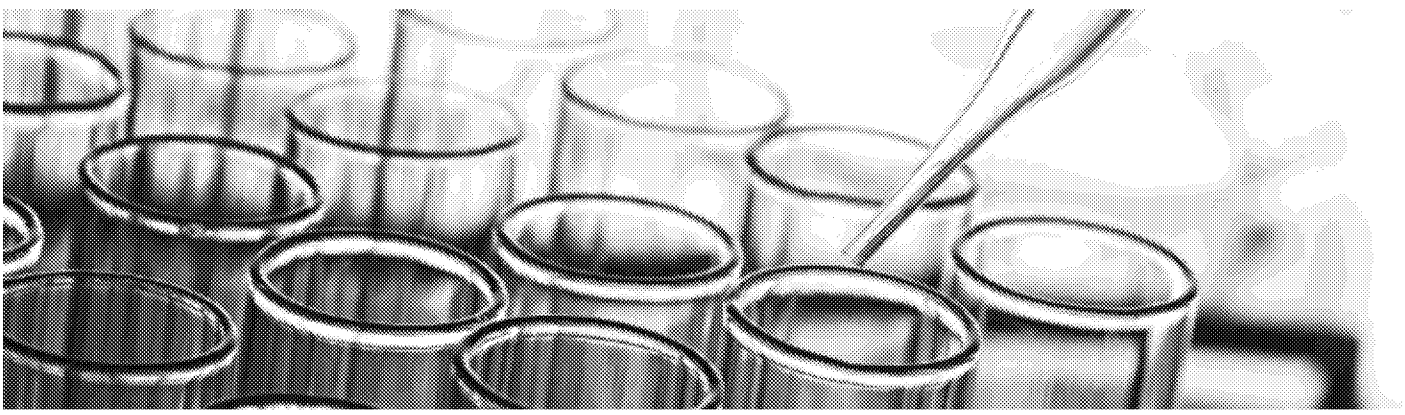
Further Information:

- Data Commons Website

REACH & CLP Hub: Keeping up with REACH

Global Business Briefing, February 2019 / Cosmetic products Regulation, Europe, REACH

Dr Friederike Danneberg of Dr Knoell, based in Mannheim, Germany, discusses the key points producers, importers and suppliers of articles need to know about SVHCs and finished goods



Six new substances were added to Echa's SVHC candidate list on 15 January, reminding us that REACH is not only about chemicals and mixtures but also applies to articles (finished goods).

While this fact has mainly interested NGOs in the past, obligations concerning articles under REACH are becoming more widely known.

Article producers, importers and suppliers are confronted with numerous questionnaires from customers and compliance statements by their suppliers. National authorities increasing enforcement activities on chemicals in articles have certainly contributed to this development. An example of such work is the enforcement project REACH-En-Force-4 (Ref-4) whose main focus is restrictions on substances in articles.

SVHC obligations

Although attention to articles has grown under REACH, knowledge of the actual obligations under the legislation is lacking. What does the presence of a SVHC in an article mean for a company?

'Although attention to articles has grown under REACH, knowledge about the actual obligations under the legislation is lacking,' Dr Friederike Danneberg, Dr Knoell

First, companies need to know whether the concentration of the substance is above 0.1%. This not only applies to a final article but – in the case of complex articles – to every single part of it.

If the concentration is above the threshold value, information about the presence of this substance and on the safe use of the article has to be communicated down the supply chain (REACH, Article 33).

If the total amount of the SVHC contained in the products exceeds one tonne per year, article producers and importers must notify Echa (Article 7(2)). As long as all obligations concerning SVHCs are fulfilled, marketability is not affected. However, as the use of the substance may become subject to authorisation in the future, it might be a good idea for companies to look for possible substitutions.

Restrictions and authorisation obligations

While SVHCs are usually part of compliance questionnaires and statements, other obligations concerning articles are often overlooked. Producers of articles should be aware that 43 of the 197 SVHCs on the candidate list are subject to authorisation and cannot be used (for example, incorporated into an article) without this, after the sunset date.

Article importers are free from this requirement as they do not "use" the substance. However, they, too, should be aware of another key part of REACH: restrictions.

Annex XVII of REACH restricts the use and presence of hundreds of substances, as many entries cover whole groups of these. Some of the restrictions only apply to substances and mixtures but many are also valid for articles – sometimes articles in general, sometimes only specific product groups like jewellery.

Phthalates: closing the loopholes

Echa is using all of the above-mentioned obligations to close loopholes concerning groups of substances, such as DEHP, DBP and BBP, three phthalates previously used widely as plasticisers.

On the candidate list from the very beginning of REACH, they have been subject to SVHC requirements since 2008. They are also listed in REACH Annex XIV and subject to authorisation.

These measures did not prevent imported articles containing DEHP, DBP and BBP from flooding the European market, so a restriction for toys and childcare articles was introduced (entry 51 of Annex XVII).

This has been expanded to articles in general, with only a few exemptions. An additional restriction that includes DIBP will be effective from July 2020.

'Companies should start looking for alternatives as soon as they become aware of the presence of an SVHC in one of their articles,' Dr Friederike Danneberg, Dr Knoell

This example shows that the addition of a substance to the candidate list is often only the first step – so companies should start looking for alternatives as soon as they become aware of the presence of an SVHC in one of their articles. This will also help to prevent losing customers that shy away from products containing them.

Know your articles

In spite of pressure from Echa to phase out the three phthalates, many noncompliant products are being marketed and may end up on the EU's Rapid Alert System for dangerous products (Rapex) list if authorities find them.

While some companies may import these products knowingly, others simply do not know their products well enough. Knowing the exact composition of an article is, of course, the easiest way to keep up with the twice yearly additions to the candidate list, or new restrictions that can be added to Annex XVII at any time.

Full material knowledge is difficult for producers of complex articles with parts coming from various suppliers and almost impossible for importers of articles, however.

For those companies, active communication up the supply chain, agreements with suppliers and – when there is no other option – testing for certain SVHCs is critical, because they are liable for fulfilling their obligations under REACH.

And it is not only REACH that regulates the use of chemicals in articles. Suppliers should have their eyes on Regulation (EC) 850/2004 on persistent organic pollutants (POPs) and know other regulations that apply to their product types, for example, the RoHS Directive for electrical and electronic equipment (EEE).

Lead: false friends

Compliance with regulations and directives is difficult and most often a laborious process. In addition, lack of knowledge on obligations can lead to a false feeling of security.

This may be the case for many suppliers of electrical and electronic devices. As their products already have to comply with the RoHS Directive 2011/65/EU which prohibits – alongside other substances – the use of lead, many might have ignored the addition of lead to Echa's candidate list in June last year, assuming their products do not contain it.

This assumption may be incorrect, however. The RoHS Directive has a huge number of exemptions for the use of lead and these are used for a great number of products. Thus, importers and retailers of EEE in particular should make sure they are informed of the presence of lead in articles by their suppliers.

Ecolabels: staying one step ahead

One option, not only to keep track with regulatory changes but to stay a step ahead, is to apply for an ecolabel and ensure products meet their requirements.

There are various ecolabels for numerous types of articles. In the EU, the most well-known are probably the EU Ecolabel, the Nordic Swan and the Blue Angel or – for textile articles – the STANDARD 100 by OEKO-TEX®.

These not only require compliance with existing legislation but prohibit the use of chemicals that, due to their hazardous

properties, are likely to become subject to regulatory obligations in the future, thereby focusing on substances relevant to the specific product group.

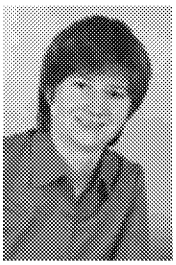
To carry the label, SVHCs are usually prohibited above a concentration of 0.1%. Companies adhering to their criteria are likely to be, therefore, less easily caught out by new restrictions on chemicals.

Conclusion

Ensuring that articles comply with relevant chemical regulation like REACH is an ongoing process. Complicated supply chains, insufficient information and overlapping legislation are only three of the problems producers, importers and suppliers of articles may face.

Solutions are easy to discuss but harder to achieve. They include staying up to date on regulatory changes, keeping informed about chemical substances in your supply chain, and trying to stay ahead of new developments – for example, by meeting requirements for an ecolabel.

Phasing out critical substances will not only help fulfil legal obligations, it will also strengthen your customer's trust in the brand.



Dr Friederike Danneberg

Dr Knoell Consult

Related Articles

- Six SVHCs added to REACH candidate list
- Echa outlines activities to promote SVHC substitution

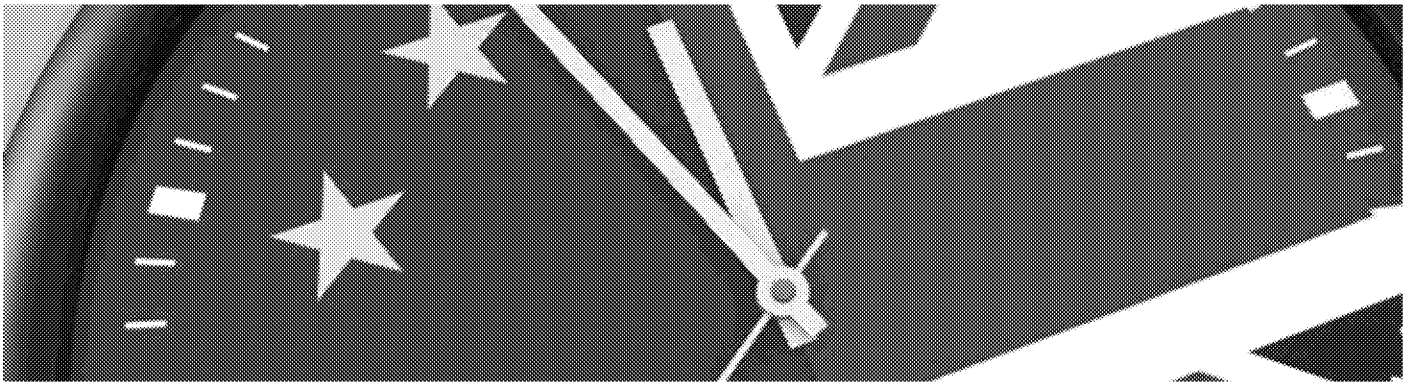
Further Information:

- Echa candidate list
- Echa's list of 96 substances to evaluate in 2019-2021
- REACH legislation

Guest Column: Will Brexit return control to the UK chemical sector?

Global Business Briefing, February 2019 / Chemical manufacturing, Data, Europe, REACH

John Hibbs, business development manager at Belgium-based Solvay and chair of the British Association for Chemical Specialities (Bacs), discusses Bacs' concerns for a no-deal Brexit, data sharing and the future of EU-UK trade post 29 March



The Bacs position is that we fully recognise the need for an effective chemicals management system for the UK. And we welcomed the 'cut and paste' approach to this because it is potentially the least disruptive way to establish a national regulation. We know that the majority of our members have supply chains that cross international borders, mainly with the EU. Replicating REACH in the UK means less work and therefore a more efficient and cost-effective compliance effort.

Where the current proposals create issues is the request to provide a "full data package" within two years of leaving the EU.

For the original EU REACH registration, registrants did not submit a full data set, but purchased a letter of access which entitled them to use data owned by third parties, to support their registration.

Defra [the UK Department for Environment, Food and Rural Affairs] knows that this data exists, and has been a part of the process of collecting and evaluating it. Data summaries and the outcomes of these evaluations are freely available.

The reasoning for asking for full data submission is far from satisfactory. It has ranged from "a legal requirement" – please show us the legal arguments – to "we are transferring the principle of no data, no market" from EU-REACH. The data exists, and the industry classifies and manages its substances according to that already submitted, so this seems a weak argument.

Defra's 'cake and eating it' policy

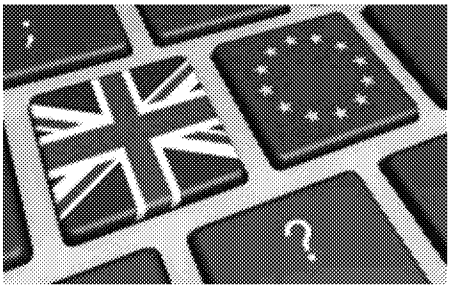
We are also seeing suggestions that UK-REACH would waive this 'legal necessity' where providing data would involve animal testing. Abhorrent as it may be, animal data is still the only data regulators will accept for more complex endpoints – which often relate directly to human health and environmental impacts.

It has been suggested that Defra would not ask for new data to be generated, if a UK registrant is unable to access the original data used for REACH. How is this consistent with a legal necessity to hold data? This could be seen as a 'having your cake and eating it' policy.

Bacs has no objection to dual submission for new registrations, assuming that the data requirements stay reasonably aligned. The burden in terms of work and cost for UK industry to resubmit data for existing registrations seems totally disproportionate to the benefits (which are zero to industry, and very poorly defined for the regulators!).

We see that incurring additional costs (which we have estimated as averaging £70,000 per substance, per company), plus the resource demands will further reduce the competitiveness of UK chemical businesses, at a time when they will

already face the disadvantage of extra duties on raw materials and export sales. We expect that the costs involved could make some substances commercially unviable for the UK market.



One-sided proposals

We have also expressed strong concerns about the one-sided nature of the proposals. The UK government is making it easy for EU companies to continue to sell into the UK after Brexit. Current guidelines would give an EU-based company 180 days to complete an only representative (OR) registration. Alternatively, they can provide limited data to their UK customers (who would notify their use), which would give at least two years of cost-free access to the UK market. No reciprocal arrangement has been made with the EU. And in the event of an exit without a deal, trade from the UK into the EU in chemicals and chemical products would stop overnight.

'In the event of an exit without a deal, trade from the UK into the EU in chemicals and chemical products would stop overnight,' John Hibbs, Bacs' chair

Bacs is also concerned by the logistics of the proposal. EU-REACH was implemented over a 12-year period – from the adoption of the Regulation in 2007 to the completion of the registration phase-in last year.

UK-REACH suggests that a task, similar in scale and complexity, can be accomplished in two years on a completely unproven IT system. The UK scheme places a high reliance on downstream users becoming importers, and therefore registrants.

From discussions with Bacs members, 'formulator' companies have neither the skills nor the resource to undertake the additional duties – they range from small businesses importing and reselling gardening chemicals, which have no regulatory resource, to large consumer goods companies which become responsible for their portfolio of 1,000 substances. The numbers just don't add up.

A no-deal UK-REACH

In all of our dealings with government and regulators, discussions on the hard practicalities of UK-REACH have tended to emphasise that this is a fall-back scenario in the unlikely even of a no-deal exit, and that government is fully committed to maintaining access to Echa membership. As a result, companies have taken very few steps towards the implementation of UK-REACH. We note that recent guidance has removed the word "unlikely".

A key frustration for all trade associations is the extreme uncertainty about what happens after 29 March. If we have a transitional period, then there will be at least two years of relative stability in which to plan and make changes. In a no-deal scenario, then major changes need to happen very quickly at substantial cost.

'To have put concrete steps in place for a no-deal would have been a pure gamble, and potentially a very expensive one,' John Hibbs, Bacs' chair

Bacs has been unable to give any clear guidance to its members, other than understanding their supply chain and considering what impact a no-deal exit could have. To have taken concrete steps for the eventuality of a no-deal would have been a gamble, and potentially a very expensive one.

Post-29 March worries

My greatest concern is the possibility of a no-deal, bringing the potential loss of EU-REACH registration (and therefore access to the EU market) for UK exporters. The chemicals sector is the UK's second-largest generator of export revenue, with the EU its biggest export market.

The current proposals give no credible mechanism for that trade to continue without major disruption in the event of no-deal. EU companies will continue to sell into the UK without regulatory barriers, while UK companies are potentially unable to sell into the EU until new registrations are in place.

Taking back control? It seems not.

The views expressed in this article are those of the expert author and are not necessarily shared by Chemical Watch.

John Hibbs

View transparency statement

Related Articles

- Feature: Chemical sector struggles with Brexit's UK-REACH data 'nightmare'
- No-deal Brexit: industry alliance warns of £1bn REACH data cost
- UK government publishes no-deal Brexit REACH notice
- UK releases additional no-deal Brexit REACH guidance

Further Information:

- UK Draft Agreement on withdrawal from the EU

Feature: Chemical sector struggles with Brexit's UK-REACH data 'nightmare'

Global Business Briefing, February 2019 / Data, Europe, REACH

British politicians 'confused' over data-sharing principles ten weeks before UK Brexit

The prospect of a no-deal Brexit is creating turmoil for chemical companies who must decide whether to spend millions buying rights for UK-REACH data they might not need, or wait for an EU exit deal that may never materialise.

If Britain leaves the EU without an agreement, companies operating in the UK will need to register under a new UK-REACH system at a cost, on average, of about £70,000 per substance, per company, the British Association for Chemical Specialities (Bacs) estimates. The total bill could rise to £1bn (€1.13bn).

Conversely, should the UK sign a deal, chemical companies may not have to pay anything at all if Britain can negotiate a data-sharing agreement with Echa.

'The biggest legal nightmare flows from the prevailing uncertainty about whether there will be a deal or no-deal outcome, two very different outcomes which makes it harder for companies to decide how best to react,' says Pinsent Masons lawyer Guy Lougher

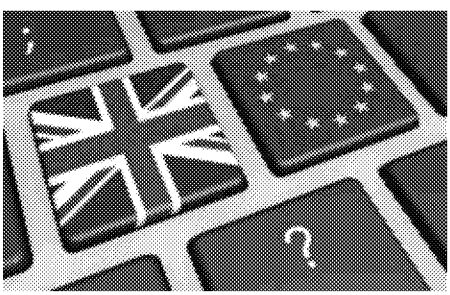
"The biggest legal nightmare flows from the prevailing uncertainty about whether there will be a deal or no-deal outcome, two very different outcomes which makes it harder for companies to decide how best to react," says Pinsent Masons lawyer Guy Lougher.

As a minimum, lawyers are telling clients to review their rights to access data required for UK-REACH, analyse the supply chain and assess their needs. Some companies may want to set up a company in continental Europe, while others will need to negotiate data-sharing agreements for the UK, but there is no one-size-fits-all solution.

"The frustrations are coming through loud and clear and some of the language is getting rather choice," says Peter Newport, chief executive of the Chemical Business Association (CBA).

"I've known normally sanguine and measured people getting very hot under the collar ... They cannot plan a way out of it without potentially wasting large sums of money doing preparatory work that might suddenly become totally unnecessary."

The UK's Health and Safety Executive has offered guidance for companies and Echa will expand on its advice in the coming weeks (see box below) but the situation is changing rapidly.



Bubbling disputes

With only ten weeks to go, all eyes are on Prime Minister Theresa May and the UK parliament this week. Tuesday's 'meaningful' vote is expected to determine whether or not MPs support Mrs May's Brexit deal, which outlines the terms of Britain's EU exit and a declaration on the outline of future UK-EU relations.

In the event of a deal, chemical companies can defer data decisions during the two-year transitional stage while Britain seeks to maintain an associated membership of Echa, which oversees the registration of European chemical data.

"Companies won't have to do anything at first, but they will need to keep it [data decisions] in mind because as we approach the end of the transitional period we could still be facing a no-deal scenario," says Anita Lloyd of law firm Squire Patton Boggs.

If Britain fails to either approve a deal, revoke Article 50 or come to another arrangement by 29 March, chemical companies doing business in the UK will have to provide initial information on substances for a new UK-REACH regime within 60 or 180 days, depending on their circumstances, and the full data package within two years of Britain leaving the EU.

Cefic expects REACH compliance problems in a no-deal scenario to hit all sectors, up and downstream, and all companies having businesses in the EU-27 and the UK: "There is a high risk that value chains will be disrupted," Cefic said in a statement.

"The time periods foreseen in UK-REACH to receive a full registration are challenging for UK-based producers and importers and even more so for non-UK based suppliers, who have to rely on only representatives [ORs] or the respective importers into the UK for registration purposes," the chemical industry association said.

While the UK government is keeping time frames for UK-REACH registration under review, the more pressing problem for many companies is that they don't own full datasets about their substances and acquiring legal rights is not straightforward.

Negotiating the minefield

EU-REACH is based on a joint registration for one substance, so many entities purchased a letter of access to data, entitling them to use data owned by third parties to support their registration. The arrangement allows them to avoid unnecessary animal testing.

The access letters don't automatically confer rights on companies who might need to register chemical data for a UK-REACH system under a no-deal scenario, however. Entities need to do an audit, if they haven't already, to determine what their data-sharing agreements allow, lawyers say.

BASF, the world's largest chemical producer, headquartered in Germany, says its biggest data concern is about gaining access to data for UK-REACH registrations that it does not already hold.

"Our experience shows that data-sharing negotiations can be lengthy and it is BASF's preference to obtain access to existing data rather than repeating studies, especially animal studies," Neil Hollis, BASF's UK REACH coordinator, told Chemical Watch.

"Considering that EU-REACH registration dossiers regularly contain data possessed by multiple data owners, it's not even a case that for each substance you are only negotiating with one data owner," Mr Hollis says.

BASF has conducted a supply-chain analysis and says it is aware that to maintain access to UK markets, companies will choose to register substances in the UK they did not previously register under EU-REACH.

"These companies will be challenged without experience or knowledge in working in these particular EU-REACH Siefs and joint registrations. Simply finding who are the data owners of these substances may be a time-consuming task," Mr Hollis says.

Company options

Some UK businesses have started registering companies in the EU, identifying ORs or looking to their EU importers to become the EU registration holder as an importer. None of it is easy.

"In Germany, for example, if you want to set up a company, you often have to have a minimum level of capital. You would have to think about what would be the language of operating and the language of documentation," says Ms Lloyd, who is director of Squire Patton Boggs' environmental, safety and health group.

"A lot of companies are looking at either Ireland or the Netherlands as being, perhaps, the most straightforward places for a company," she adds. "It is not as simple as setting up a shell company or a post box."

Some of the more proactive businesses are assessing their data rights and planning a strategy both for obtaining access to required data, or evaluating whether there is financial benefit in the data within their ownership, says Simon Tilling of Burges Salmon law firm.

"I can see the potential for lots of challenges over access rights to data within the far too short two-year period for submitting dossiers. There is a real potential for a mess that will take far longer than two years to sort out," Mr Tilling adds.

'Project Fear'

The CBA's Peter Newport is not aware of any members who have obtained datasets from data owners as a result of existing letters of access for EU-REACH. He worries about spiralling costs.

'If we spent more than €5bn on EU-REACH, what is there to suggest it is going to be much less for UK-REACH?' – CBA's Peter Newport

"I don't like 'Project Fear'," Mr Newport says. "But if we spent more than €5bn on EU-REACH, what is there to suggest it is going to be much less for UK-REACH?"

Granted, Mr Newport says, the €5bn figure depends on the number of substances registered under UK-REACH and it could come down rapidly if companies are prepared, as data-owners, to share the data for free. He questions what incentive they'd have to do that, however.

Lawyers expect it is just a matter of time before more problems emerge.

"There is a real concern among my clients and contacts that the UK government has not got to grips with data sharing under EU-REACH," Mr Tilling says.

"Statements from ministers in the past year have betrayed a confusion over what the data-sharing principles of EU-REACH actually mean, muddling up 'access to data' with 'data ownership', and assuming that dossier submissions for UK-REACH is a bureaucratic exercise when the barriers are far more substantive."

A House of Lords sub-committee scrutinising the Department for Environment, Food and Rural Affairs' (Defra) no-deal Brexit preparations in 2018 said they were "disturbed to hear" from environment minister Michael Gove that he was not aware of many of the issues surrounding chemical regulations post-Brexit.

In response to the complaints, Defra told Chemical Watch that the government has already issued technical notices with no-deal Brexit advice and is "committed to maintaining an effective regulatory system for the management and control of chemicals which safeguards human health and the environment, and can respond to emerging risks. This will not change when we leave the EU".

'Unveiling the UK-REACH IT system'

Under the no-deal scenario, chemical companies worry they won't just have to enter into new data-sharing agreements, but may also have to also upload the datasets into a UK-REACH IT system that's still a work-in-progress.

EU-REACH was implemented more than a decade ago, from the 2007 adoption of the regulation to the completion of the registration phase-in in 2018.

"UK-REACH suggests that a task, similar in scale and complexity, can be accomplished in two years on a completely unproven IT system," says Bacs chair John Hibbs.

The UK scheme relies on downstream users becoming importers, and therefore registrants. But after talks with Bacs members, Mr Hibbs says "formulator" companies don't have the skills or resource to undertake the additional duties.

"These range from small businesses importing and re-selling gardening chemicals, who have no regulatory resource, to large consumer goods companies who become responsible for their portfolio of 1,000 substances. The numbers just don't add up."

The CBA was told in December that the pilot version of UK-REACH only covers basic registration functionality, so there may also be problems with initial 60-day registration.

"There is a potential problem for people that need to register large volumes of substances, and we have asked for automated upload capability on the new system. We have not received any assurance that will be available or not," says Mr Newport.

Even if the UK-BREXIT IT system works perfectly, data-sharing and other issues could cripple some UK companies. There's still no credible mechanism for EU trade to continue without major disruption in the event of no-deal, Mr Higgs says.

"EU companies will continue to sell into the UK without regulatory barriers, while UK companies are potentially unable to sell into the EU until new registrations are in place."

Echa's advice for companies in a no-deal scenario

While Echa has already published guidance on data-sharing issues, the agency is also preparing an information package to draw companies' attention to the steps they will need to undertake ahead of a no-deal Brexit.

"We are investigating the possibility to put into place changes to our IT Tools (REACH-IT) to enable UK-based companies to appoint an EU-27 OR already before 30 March," Echa told Chemical Watch.

"Simultaneously, we are putting together step-by-step instructions on what these companies need to do in REACH-IT to make the change and also advise them about the exact time frame when this can be done. We aim to publish this information by the end of this month/beginning of February."

Caroline Byrne

Commissioning editor

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- UK government publishes no-deal Brexit REACH notice
- UK post-Brexit chemicals IT system could be 'ready tomorrow'

Further Information:

- UK Draft Agreement on EU Withdrawal
- Defra's response to the House of Lords subcommittee
- Defra notice on data to be submitted in no-deal scenario
- Regulatory Policy Committee REACH document

Guest Column: Echa outlines the key priorities for 2019

Global Business Briefing, February 2019 / CLP Regulation, Enforcement, Europe, REACH, Risk assessment, Substances of concern

Björn Hansen, Echa's executive director, discusses the agency's 2019 priorities including managing the risks of substances of concern

2019 is the first year after the major regulatory deadlines of REACH and the first year during which Echa will start to implement its new strategic priorities.

'Our first strategic priority is to identify and manage the risks of substances of concern,' – Bjorn Hansen, Echa executive director

Our first strategic priority is to identify and manage the risks of substances of concern. Under this, the interplay between the registration, evaluation and risk management processes under REACH and CLP will be streamlined and will make up a substantial part of the agency's work throughout 2019.

At the same time, the two other strategic priorities – improving supply chain communication with a view to increasing safe and sustainable use of chemicals and substituting substances of very high concern, and ensuring the consistency and integration of the EU regulatory system on chemical safety – will remain at the core of the agency's work.

To this end, Echa will support industry in implementing the ENES tools, making more information on uses and exposure available and creating an effective cycle of information to manage chemicals safely. In addition, the agency will continue to implement its substitution strategy, which aims to boost the availability and adoption of safer alternative substances and technologies throughout the EU.

In 2019, we will continue pursuing robust technical solutions for managing data, building up the EU observatory for nanomaterials, taking the first steps towards an EU legislation finder on chemicals, and building on the successful start in developing occupational exposure limits.

Ensuring REACH compliance

The REACH Review carried out by the European Commission concluded that REACH is an effective instrument, but not yet working efficiently enough. It highlighted several areas of REACH where improvements are needed, and 2019 will see us move more concretely to putting such actions into practice.

One of the key improvements we need to make in 2019 is to do more to ensure REACH compliance.

Back in October 2018, the German Federal Institute for Risk Assessment (BfR) published a report which showed that around one-third of registration dossiers in the highest tonnage bands do not comply with REACH requirements. This is a message that we hear loud and clear from various sources, but also echoes our own findings.

More compliance checks ahead

Checking the regulatory compliance of registration dossiers has been one of Echa's core tasks since the early days of the agency. However, it has become clear that the 5% compliance check of registration dossiers in each tonnage band has not had the desired effect.

Back when REACH was being developed, a certain level of non-compliance was expected, but the issue here is the extent.

The crucial point about non-compliance is that there may be some effects of a chemical that go unnoticed. While this is not the case for all non-compliant dossiers, it is an underlying cause for concern.

'We will focus more heavily on compliance checks, making it an agency-wide priority,' – Bjorn Hansen, Echa executive director

In 2019, we will therefore need to focus more heavily on compliance checks, making it an agency-wide priority. This means freeing up resources to carry out more dossier compliance work, and making the most of our staff's experience to increase efficiency.

In addition, we will interact and collaborate more proactively with sectors on groups of substances, aiming to come up with solutions to dossier compliance issues which can reduce or eliminate the need of further regulatory steps.

Restriction and authorisation processes

Another aspect of the REACH Review that we will concentrate on during 2019 is clarifying and improving the restriction and authorisation processes.

In practice, we will identify which points in the restriction dossier or authorisation applications are crucial for determining the outcome and where more information is needed.

We believe that having a better understanding here will enable more straightforward decision making.

Achieving this will require greater levels of cooperation with the Commission, Member States, experts, NGOs and industry, and discussions on how to achieve this are already taking place.

The activities implementing BPR and PIC [Biocidal Products Regulation and Prior Informed Consent Regulation] will continue to be as important as ever in ensuring the safe use of substances. We expect intensified assessment of biocidal active substances with potential endocrine-disrupting properties, and continued increases in the number of PIC export notifications during 2019.

Finding ways to be efficient

While working on these areas, we will also be adjusting to our new organisational structure. The changes to our structure better reflect our working environment, and will help us take on new tasks and face future challenges.

One such challenge is, of course, the need for resources. We are a large agency with the potential to do a lot of good work, but there are limitations to how much more we can do without increasing our resources.

The reorganisation will help us to find ways to be more efficient and effective and to develop staff competence to handle the existing workloads under REACH, CLP, Biocides and PIC as well as integrate the new tasks we receive – but to make a real difference, we need to re-discuss the resources at our disposal.

Brexit

Another element we are facing is the UK's imminent withdrawal from the EU. We are fully prepared for this and have been informing industry both in the UK and in the remaining EU-27 of the things they need to consider and act upon.

So, we have a fully packed agenda for 2019 – but I am confident that together we will manage it successfully.

Björn Gaarn Hansen

Executive director, Echa

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Further Information:

- REACH review

Expert Focus: Has Beijing's new draft regulation introduced China-REACH?

Global Business Briefing, February 2019 / China, REACH

Heng Li, a senior associate at Mayer Brown law firm in Beijing, compares China's latest draft chemical regulation with EU-REACH to determine the impact it will have on companies

China has introduced a groundbreaking draft law covering all existing and new chemical substances, a big change from the past decade where regulators focused on new substances, especially under the ambit of the Ministry of Ecology and Environment (MEE).

The MEE published the draft Regulation on the Environmental Risk Assessment and Control of Chemical Substances on 8 January, with public comments accepted until 20 February.

The wide-ranging draft will affect companies manufacturing, processing and using, importing and exporting chemicals in and from China. It covers the environmental risk assessment and control of chemical substances, and offers a preview of changes that may be incorporated into China's new substances management regime.

When the text of the draft law was unveiled, some in China referred to it as the 'real' China-REACH. This article examines the draft in detail to determine whether that description is accurate and what companies need to know about the changes.

China's changing laws

A single chemical is now regulated by a variety of laws and Chinese authorities depending on its legal status as, for example, a new, existing, or hazardous chemical.

The MEE has promulgated MEP Order 7, which has been in effect since 15 October 2010 and is now being revised. It introduces REACH-like requirements for the registration of new chemical substances but has a different scope from EU-REACH, which covers existing and new chemical substances.

The ministry has been laying the groundwork for the regulation of existing chemical substances since 2016. China drafted the technical guidelines for screening chemicals subject to prioritised assessment and it issued the first batch of priority control chemicals in 2017. The changes indicate that the MEE does not intend to regulate all types of existing substances, focusing instead on those that are prioritised.

The draft Regulation is expected to become the overarching legislation governing existing and new chemical substances but with an emphasis on the control of environmental risk. This is defined as "the degree and probability that a chemical substance with environmental or health hazard properties will enter into the environment and cause harmful effects on the ecological environment and human health".

Since the draft Regulation is likely to be promulgated by the State Council pursuant to China's Legislative Law, its legal effect is expected to be superior to the departmental rules promulgated by the relevant ministries (including the revised MEP Order 7), reflecting the MEE's intention to intensify the regulation of chemicals.

'Its legal effect is expected to be superior to the departmental rules promulgated by the relevant ministries, including the revised MEP Order 7, reflecting the MEE's intention to intensify the regulation of chemicals,' Heng Li, Mayer Brown

Important points for companies

There are several key features that companies may want to consider.

The draft Regulation governs both existing substances and new substances that are not included in the Inventory of Chemical Substances of China (ICSC). The MEE will establish and update the ICSC, which is newly introduced in the draft. It is likely to be based on the current Inventory of Existing Chemical Substances of China (IECSC). It is not clear if the ICSC will include all of the existing substances in the IECSC, however.

The draft will not apply to substances "used for laboratory-scale research or reference standards", but there is an exception for new chemical substances manufactured or imported in quantities at or above 100kg/year. While the phrase "used for laboratory scale research or as reference standards" is not defined, this may be clarified in the implementation rules or MEE guidelines.

Draft highlight

The draft Regulation highlight involves the provisions on environmental risk assessment and control, which apply to any 'chemical substance', not distinguishing between existing and new substances.

'The draft Regulation highlight involves the provisions on environmental risk assessment and control, which apply to any chemical substance, not distinguishing between existing and new substances,' Heng Li, Mayer Brown

In essence, the draft requires the MEE to organise the environmental risk assessment of chemical substances subject to prioritised assessment, based on information acquired through industry reporting and specific activities carried out by the MEE, including environmental risk screening.

Any company manufacturing, processing and using, and importing a chemical substance would need to provide the MEE with an annual report including basic information about the substance, including its name, quantities and uses.

As part of the environmental risk screening, the MEE is to establish a plan for the risk assessment of chemical substances subject to prioritised assessment. Companies manufacturing, processing and using, and importing a substance in the plan would need to provide information, including data on emissions, physico-chemical properties, toxicology and eco-toxicology.

Once the risk assessment is complete, the MEE will promulgate the relevant risk control measures, along with other ministries, to establish:

- a catalogue of chemical substances subject to prioritised control (the Prioritised Control Catalogue, or PCC), including substances that must abide by additional laws such as the Prevention of Atmospheric Pollution, of Water Pollution and of Soil Pollution Laws;
- a catalogue of restricted chemical substances (the Restriction Catalogue), including substances selected from the PCC subject to restrictions on uses and relevant import/export licensing;
- a catalogue of prohibited chemical substances (the Prohibition Catalogue), including substances selected from the PCC that would be strictly prohibited from being manufactured, processed and used, imported and exported in and from China; and
- an Information Publication Platform for Chemical Substances Subject to Prioritised Control requiring companies to disclose information annually.

Key changes for new substances

The draft Regulation reveals key changes that are likely to become part of China's substance management regime. These are:

- new substances would be subject to registration or filing. The current requirement of simplified registration provided by MEP Order 7 appears to be replaced by the filing process;
- registration would apply to the new substances that are manufactured or imported at or above one ton/year;
- filing would apply to the new substances below one ton/year (except for the new substances which are "used for laboratory scale research or as reference standards" and are below 100 kg/year) and the other specified substances (for example, low-concern polymers);
- the application for the registration of persistent bioaccumulative toxic chemicals (PBTs) and "the substances possessing the same hazards" would be rejected, and they would be included in the Prohibition Catalogue; and

- registration would be subject to a fee payable to the MEE.

The draft Regulation maintains the statutory timeframe for inclusion of a registered new substance into the ICSC, which is five years after completion of the registration. In addition, the draft empowers the MEE to provide, in the ICSC, the restrictive conditions on the uses of certain substances where necessary.

Enforcement

The draft Regulation introduces the possibility of severe penalties for companies manufacturing, processing and using, and importing and exporting chemicals in and from China.

'A company failing to complete the required new substance registration could face an administrative fine of up to RMB2,000,000 ($295,000),' Heng Li, Mayer Brown

For example, a company failing to complete the required new substance registration could face an administrative fine of up to RMB2,000,000 ($295,000), compared with a fine of up to RMB30,000 under MEP Order 7. In the most severe cases, they may be ordered to cease business. Companies are encouraged to submit their comments before the public consultation deadline in February.

Rapid promulgation of the legislation is not expected, given China's legislative priorities and the need to align the interests of the various affected ministries before the State Council can take action.

The draft may also be revised and subject to additional consultations leading up to its promulgation, so companies should submit comments if they want to propose changes or introduce new provisions.

It is vital that companies actively monitor the enactment of the implementation rules of the draft. While the draft Regulation introduced general requirements, many detailed requirements must be specified by the relevant departmental rules and official guidelines to be promulgated by the MEE and other ministries.

These include:

- the definition of technical terms such as PBTs and 'substances possessing the same hazards';
- the detailed procedure of environmental risk assessment and control, specifically whether the industry would be provided with opportunities to defend their products;
- the protection of CBI; and
- detailed requirements on new substance management to be provided in revised MEP Order 7 and the associated official guidelines.

Companies are also encouraged to assess the draft Regulation's impact on their products, supply chain organisation and global compliance strategy from a legal and regulatory standpoint at the earliest possible stage.

The 'real' China-REACH?

There are certainly REACH-like elements in the draft Regulation. Like EU-REACH, it governs existing and new substances.

The environmental risk assessment process also appears to be similar to substance evaluation under EU-REACH, where the MEE will play a dominant role and could ask industry to submit additional data.

Furthermore, the process for including a substance in the Restriction Catalogue is similar to the restriction process under the European law. Both are risk-based and are initiated by the authorities.

But the draft Regulation differs in other respects.

While the draft covers only environmental risk, EU-REACH covers all types of risks, including those caused by the physical and health hazards of a chemical substance.

The draft requires the registration or filing of new substances only, irrespective of the tonnage. EU-REACH, however, requires the registration of existing and new substances at or above one ton/year.

China's draft Regulation introduces the inclusion of a substance in the Prohibition Catalogue but it doesn't provide an authorisation process. Listing in the catalogue would result in a ban on its manufacturing, use, import and export in and from China. Under EU-REACH, however, even if an SVHC is included in Annex XIV the industry can apply for an authorisation to continue its use(s) in the EU.

In summary, the draft Regulation has REACH-like elements but it cannot be considered 'China-REACH'.

The differences between this legislation and EU-REACH, and its relationship with the other laws in China, reflect the unique nature of the country's legal and administrative systems. Chinese legislators take this into consideration when drafting legislation.

The views expressed in this article are those of the expert author and are not necessarily shared by Chemical Watch.

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Heng Li

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Further Information:

- China's draft Regulation
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